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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,451	11/03/2003	Annibale Salvi	P-6320-US	3464

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EXAMINER

SACKEY, EBENEZER O

ART UNIT PAPER NUMBER

1626

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,451	<b>Applicant(s)</b> SALVI ET AL.	
	<b>Examiner</b> EBENEZER SACKY	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13 is/are allowed.
- 6) ☒ Claim(s) 1-6 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/03/03, 5/21/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### **Status of the Claims**

Aims 1-14 are pending.

### ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Information Disclosure Statement***

Receipt of the Information Disclosure Statement filed 11/03/03 and 05/21/04 respectively is acknowledged and has been entered into the file. Signed copies of the 1449 are attached herewith.

**Claim Rejections - 35 U.S.C. § 103**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

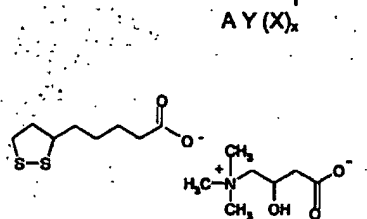
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 1-6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ames et al., (U.S. Patent number 5,916,912)('912') and (French Patent number 4,512 M)('512') each taken alone in view of Ekwuribe et al., (U.S. Patent number 6,479,692)('692').

Applicants claim salts of structural formula depicted in claim 1, wherein the substituents



are as defined in claim 1

Ames et al., and French Patent 4,512 M, disclose salts structurally similar to the instantly claimed salts. See the entire references especially column 1, lines 35-47, of Ames et al., and page 1, column 1 the last example of '512'.

The instant claims differ from '912' and '512' in that the references disclose the free acid form of the compounds whereas the instant claims are drawn to the alkaline metal, alkaline earth metal salts and quaternary ammonium of the compounds. However, Ekwuribe et al. discloses that salts such as alkaline metal salts, alkaline earth metal salts are salts that retain the desired biological activity of the parent compounds. See column 11, lines 15-30. Thus, there is ample motivation for one of ordinary skill in the art to modify the prior art compounds to arrive at the instantly claimed salts because Ekwuribe et al., discloses that pharmaceutically acceptable salts are salts that retain the desired biological activity of the parent compounds and do not impart undesired toxicological effects. See column 11, lines 15-17.

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The motivation to prepare these compounds derives from the fact that the resulting salt would reasonably be expected to be useful for dietary composition for enhancing metabolism in humans and animals since Ekwuribe et al., discloses that pharmaceutically acceptable salts retain the desired biological activity of the parent compounds and do not impart undesired toxicological effects. Therefore, the instantly claimed salt would have been suggested to one of ordinary skill in the art absent a showing of unobvious results and/or properties.

Claims 7-13 are allowed over the prior art of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704.

The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is

(571) 272-1600.

EOS

November 28, 2005

  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1600  
Technology Center 1